EXHIBIT 5

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February 14, 2019

Corey L. Gordon, Esquire
Blackwell Burke P.A.
431 So. 7th St. Suite 2500
Minneapolis, Minnesota 55415

Re: **Ada Trombley v. 3M Co., et. al.**
Bair Hugger Forced Air Warming
Products Liability Litigation

Dear Mr. Gordon:

At your request, in preparation for the following report concerning the matter above-mentioned, I have reviewed the following materials, in addition to what was reviewed for prior reports:

1. Plaintiff's Reports

- Report of Dr, William R. Jarvis
- Report of David Yadin
- Report of Dr. Eric Brown

2. Depositions

- Dr. Karl Beer
- CRNA Lauren Peterson
- Dr. Nicolasura Deposition
- Dr. Tammam Abdul-Aziz
- Dr. Bradley Everly
- Ada Trombley

3. Ada Trombley Medical Records

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4. ***Further References on Infection Risk for Patients, Infection Risks in the Operating Room, and others as may be noted in the body of this report***

MY BACKGROUND

I am an orthopaedic surgeon, board certified by the American Academy of Orthopaedic Surgeons (AAOS). I received my medical degree from the University of Pennsylvania in 1984. From 1984 to 1989, I did a research fellowship, followed by an internship, and then an orthopaedic residency at the Mt. Sinai Medical Center, Department of Orthopaedics, in New York City. From 1989 to 1990, I completed a one-year fellowship in lower extremity joint reconstruction at the Johns Hopkins University Medical Institutions, Department of Orthopaedics in Baltimore, Maryland. Following this, I stayed on the full-time orthopaedic faculty at Johns Hopkins from 1990 to 2000 as an Assistant and then as an Associate Professor of Orthopaedic Surgery. In 2000, I co-founded the Rubin Institute for Advanced Orthopedics at Sinai Hospital of Baltimore and became the Director of the Center for Joint Preservation and Replacement. I held this position through June of 2016 and had become an Adjunct Associate Professor of Orthopaedic Surgery at Johns Hopkins. As of July 2016, I assumed the position as Chairman of Orthopaedic Surgery at the Cleveland Clinic, Cleveland, Ohio. There, I became an adjunct Assistant Professor at Case Western University in December of 2017. I stepped down as Chair at Cleveland Clinic in 2018, but continue in an advisory role as adjunct staff. In April of 2018, I began as a staff orthopaedic physician at Lenox Hill Hospital, New York, New York, and serve as Vice President of Strategic Initiatives, Orthopedic Service Line and System Chief of Joint Reconstruction for Northwell Health, Inc. in New York.

I routinely take care of lower extremity joint replacement patients in that I have performed during my professional career from 500 to 700 joint replacement surgeries per year for a total of over 15,000 since 1990 (except for the year and a half period as Chairman of Cleveland Clinic Orthopaedics, where my clinical duties were reduced by 50%), and recently in building a new practice in New York City this past year. I had typically seen over 6,000 patients per year with approximately half related to the knee. Presently, I am now back to performing full-time duties in orthopaedics, in addition to my administrative roles.

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I have been course director of many local, national, and international meetings that deal with knee replacement surgery. Through these meetings, as well as with my training and experience, I know the standard of care for treating patients with multiple medical and surgical issues, including known complications from surgical procedures such as periprosthetic joint infections. This knowledge is garnered not only from my fellow panelists, but also from general orthopaedists in the audience when we go over case reports of patients who have similar issues to the ones presented in this litigation.

My other qualifications include that I am an active member of the American Association of Hip and Knee Surgeons (AAHKS), the Hip Society, the Knee Society, and the International Hip Society. I am an editor and reviewer for over ten different pertinent journals, including being the Assistant Editor-in-Chief of the *Journal of Arthroplasty*, considered to be the preeminent journal for total joint replacement surgeons. I have received numerous grants related to knee and hip replacements (greater than 100). In addition to my own original research, through collaborations with multiple national and international institutions, I have been an author on over 900 peer-reviewed PubMed publications; many of these are related to the topic of periprosthetic infections. I have extensively participated in both International Consensus Meetings on Periprosthetic Joint Infections as a delegate, contributor, group leader, and editor.

BRIEF SUMMARY OF CASE

Ms. Trombley had a left total knee arthroplasty in 2001 and had a long history of right knee painful osteoarthritis. Her comorbidities and other relevant medical conditions included Type 2 diabetes, obesity (BMI 37.55), hypertension, chronic corticosteroid use (prednisone 10 mg daily), psoriatic arthritis, anemia, gastrointestinal reflux disease, chronic analgesic and opioid use, history of rhinitis and oral problems, renal disease, history of recurrent urinary tract infections, potential malnutrition with magnesium and probable Vitamin D deficiencies, and potential great toe problems.

She underwent an apparently uneventful right total knee replacement on December 2, 2011 by Dr. Karl Beer and her hospital course appeared routine with discharge on December 4.

She was seen by Dr. Beer on December 15, 2011 for staple removal. He described her incision as "clean, dry, and intact." He noted an ecchymosis of the lower leg, but concluded that

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there was "no warmth, induration and no erythema," with no evidence of infection.

Dr. Beer saw her on January 10, 2012 after she had approximately 4 days of knee drainage. She also complained of approximately four days of fever, chills and increasing pain She had serology consistent with an infection (WBC count of 20K, CRP of 12.5 (normal up to 0.744), and a Sedimentation rate of 57 (normal up to 30). Dr. Beers attempted to aspirate the knee joint and was not able to recover any fluid. He obtained a sample of the superficial drainage just below the surface of the skin and had a Gram stain performed on it. The Gram stain demonstrated Gram-positive cocci. The culture subsequently grew moderate Group B Streptococcus (GBS) bacteria.

The next day, Dr. Beer performed an incision and drainage of this periprosthetic joint infection (PJI) on January 11, 2012 with removal of all of the components and insertion of an antibiotic-impregnated spacer. During the surgery, he obtained samples from the surgical site that were sent for laboratory analysis. The laboratory results demonstrated:

Deep wound: Gram stain: 0 WBC and no organisms seen; culture: rare GBS. Anaerobic Culture: rare GBS; no anaerobes.

Right knee synovium: Gram stain: 10 to 24 WBC and no organisms seen; Culture: few GBS. Anaerobic Culture: rare GBS, no anaerobes.

Ms. Trombley began a course of antibiotics and had her initially scheduled re-implantation surgery canceled due to dental issues. Finally, she had surgery to re-insert her prosthesis on August 31, 2012.

According to her deposition, she has not followed back up with Dr. Beer in 5 to 6 years and claims that her leg was straight and better and it was her understanding that she did not need to come back for follow-up. She claims that it is occasionally stiff, aches, and hurts (deposition, page 32). However, she describes this aching or pain as mostly at night at the end of the day, for which she mostly takes Percoset pills.

OPINION SUMMARY

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I disagree with plaintiff's expert William R. Jarvis, M.D., (November 27, 2017) as follows:

A. William R. Jarvis, M.D. (November 27, 2017):

As stated in my previous expert reports (general cause as well as Gareis and Axline), to make statements that everything went smoothly during the procedure and, therefore, it must be the Bair Hugger device that caused Ms. Trombley's infection, is a *reductio ad absurdum* argument and simply ignores the fact that virtually anything or anyone in the operating room could have in some way led to an infection. Even assuming that the infection occurred intra-operatively, which is almost certainly not the case, it is impossible to rule out all possible causes and sources of bacteria in a differential diagnosis as Dr. Jarvis claims to have done. I disagree with his opinions about the Bair Hugger, and it is my strong opinion that it is not in any way related to Ms. Trombley's periprosthetic joint infection.

The Bair Hugger should not even be in the differential diagnosis of causing this periprosthetic joint infection in Ms. Trombley. Dr. Jarvis assumes that the infection occurred intra-operatively, which is almost certainly not so, and then leaves out, or discounts, for example, the operating room staff, the spray of fluids during the case, the personnel, the potential for overlooked glove perforations/contamination, or any other clothing as well as equipment contamination. He ignores multiple other factors as well, which I will discuss later in this report. He certainly minimizes the patient's own skin which is the major source of bacterial flora. As mentioned repeatedly, even the most effective skin preparation cannot eliminate all bacteria directly on the skin or just below the skin. Bacteria accumulate during the case either by direct contact with instruments, from the space suit such as was used by Dr. Beer, the gown /glove interface, and many other sources. The Bair Hugger should not even be on the list of even remote possibilities- being behind the anesthesia curtain, completely draped off, well away from the surgical incision, just off the floor, etc.

In the case of Ms. Trombley, her surgery was performed by a surgeon who had an extremely low infection rate (0.3%---less than one half of the national average). He has performed thousands of total joint replacements and has always used the Bair Hugger device, both before and after Ms. Trombley's case.

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Dr. Jarvis' statements about ruling out the Heating Ventilation and Air Conditioning (HVAC) System, the surgical team contamination, the patient's flora, the surgical procedure and technique, and other potential causes, are unfounded. All of these areas are potential sources of bacterial contamination and could lead to a periprosthetic joint infection in any total knee replacement case. They cannot be ruled out. Evidence for all of the above as potential sources of contamination as well as many other possible sources will be presented in the following sections of this report and is in addition to what I have previously presented in my prior general cause report.

Dr. Jarvis states that her BMI is 36 based on a height of 5 feet 3 inches and a weight of 212 pounds. The correct BMI for that height and weight is actually 37.55.

Dr. Jarvis has made similar statements to the following in previous expert reports that I have reviewed: "As to biological plausibility, pathogens are the actual ***causes*** of the PJI; that is, the only biological causes of infection in the orthopedic implant arena are bacteria that have inoculated the joint. The general consensus is that PJI's that occur within 90 days and in some instances up to one year after the index surgery are most likely caused by inoculation of the joint during the surgery."

In my opinion, this is a completely misleading statement since bacteria are always around the operating room environment and no surgical wound can be sterile – we all know this. Whether bacteria are on the skin, the air, the equipment, being sprayed, etc., we are simply trying to minimize the bioburden, which cannot be completely eliminated. The comorbidities that he is discounting all enhance the chance of an infection, whether it be intra-operative, post-operative, or through hematogenous spread. Moreover, the type of infectious organism, the history of onset, its presentation, and many other factors must be considered in assessing whether inoculation more likely occurred intra-operatively or after the surgery. Reliance on an arbitrary and general guidance does not substitute for an analysis of specific factors in an individual case. When one does that analysis with Ms. Trombley, it is clear that the inoculation occurred post-operatively. See my discussion below.

Dr. Jarvis states that well-controlled diabetes does not increase the risk of an infection. This is pure speculation. I am not aware of any controlled studies that support this conclusion—

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diabetes is simply a factor that increases risk. In addition, it is impossible to know whether a well-controlled patient in the hospital does not leave the hospital and become not well-controlled. In Ms. Trombley's case, it is documented that she doesn't always take her diabetic medications. Sometimes she does not follow medical advice, such as regarding starting dialysis (Dr. Everly's depostion).

In addition, skin lesions (perhaps on her foot), oral lesions (she had bacterial infections at some points in her care), rhinitis, recurrent urinary tract infections, etc. all harbor bacteria. Any or all of these might have been relevant to Ms. Trombley's infection, which are disregarded by Dr. Jarvis.

Certain co-morbidities can also increase the bioburden. If a patient is immunosuppressed, for example, there may be more bacteria circulating in their system that have to be contended with. A patient is likely to have increased endogenous bacteria if they have multiple comorbidities as Ms. Trombley did.

Dr. Jarvis concludes, without any basis, that pathogens were deposited in the surgical wound during the surgery.

He entirely discounts the nature of this organism and many other relevant findings in this case as I will elaborate on in this report.

1. **Although it was unfortunate that Ms. Trombley had a periprosthetic joint infection, this is one of the risks of any knee replacement at a rate of about 1 to 2% nationally.**

2. **Her risk for a periprosthetic infection was compounded by various demographic risk factors that she had, including the following (not arranged in order of importance):**

A. Psoriatic arthritis

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Psoriatic arthritis, a condition from which Ms. Trombley suffered, increases the risk of surgical site infections. This disorder is one of many that can potentially increase bacterial load to the surgical site. Psoriatic plaques have been shown to harbor increased concentrations of bacteria compared with unaffected skin, causing concern for an increased risk of infection (Aly et al., Drancourt et al.). It is noteworthy that Sharp et al. performed a surgical simulation using patients with psoriasis who have increased shedding of skin. With slit-air sampling and simulated regular operating room activity, they failed to identify increased air contamination with the use of forced air warming devices.

References:

Aly R, Maibach HE, Mandel A. Bacterial flora in psoriasis. Br J Dermatol 1976;95:603–6.

Drancourt M, Argenson JN, Tissot Dupont H, Aubaniac JM, Raoult D. Psoriasis is a risk factor for hip-prosthesis infection. Eur J Epidemiol 1997;13:205–7.

Sharp RJ, Chesworth T, Fern ED. Do warming blankets increase bacterial counts in the operating field in a laminar-flow theatre? *J Bone Joint Surg Br*. 2002;84(4):486-488.

B. Oral Problems

Ms. Trombley had multiple problems with her oral hygiene, leading to her needing complete removal of her teeth (dental extractions), rendering her edentulous. In fact, her reimplantation surgery was canceled because she had to undergo these oral procedures on May 30, 2012. The oral cavity can be a source of bacteria that can cause a periprosthetic infections. Of note is that these teeth were extracted because of apparent oral infections by Dr. Krejekian. This was mentioned in Dr. Beer's deposition on page 29.

Transient bacteremia occurs following everyday activities such as tooth-brushing and flossing, as well as following dental procedures. Associated with this transient bacteremia, there is a potential risk of hematologic spread, seeding of the prosthesis, and subsequent development of periprosthetic joint infections (PJIs). Multiple small-scale studies have shown an association between bacteria isolated in PJIs and oral flora.

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References:

Bartz, H. *et al.* Micromonas (Peptostreptococcus) micros: unusual case of prosthetic joint infection associated with dental procedures. *Int. J. Med. Microbiol.* **294,** 465–470 (2005).

Bartzokas, C. A. *et al.* Relation between mouth and haematogenous infection in total joint replacements. *BMJ* **309,** 506–508 (1994).

Berbari, E. F. *et al.* Dental Procedures as Risk Factors for Prosthetic Hip or Knee Infection: A Hospital-Based Prospective Case-Control Study. *Clin Infect Dis* **50,** 8–16 (2010).
Crasta, K. *et al.* Bacteraemia due to dental flossing. *J. Clin. Periodontol.* **36,** 323–332 (2009).

Debelian, G. J., Olsen, I. & Tronstad, L. Anaerobic bacteremia and fungemia in patients undergoing endodontic therapy: an overview. *Ann. Periodontol.* **3,** 281–287 (1998).

Hartzell, J. D., Torres, D., Kim, P. & Wortmann, G. Incidence of bacteremia after routine tooth brushing. *Am. J. Med. Sci.* **329,** 178–180 (2005).

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Mougeot, F. K. B., Saunders, S. E., Brennan, M. T. & Lockhart, P. B. Associations between bacteremia from oral sources and distant-site infections: tooth brushing versus single tooth extraction. *Oral Surg Oral Med Oral Pathol Oral Radiol* **119,** 430–435 (2015).

Quénard, F., Seng, P., Lagier, J.-C., Fenollar, F. & Stein, A. Prosthetic joint infection caused by Granulicatella adiacens: a case series and review of literature. *BMC Musculoskelet Disord* **18,** 276 (2017).
Rubin, R., Salvati, E. A. & Lewis, R. Infected total hip replacement after dental procedures. *Oral Surg. Oral Med. Oral Pathol.* **41,** 18–23 (1976).

Skaar, D. D., O'Connor, H., Hodges, J. S. & Michalowicz, B. S. Dental procedures and subsequent prosthetic joint infections: findings from the Medicare Current Beneficiary Survey. *J Am Dent Assoc* **142,** 1343–1351 (2011).

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Waldman, B. J., Mont, M. A. & Hungerford, D. S. Total knee arthroplasty infections associated with dental procedures. *Clin. Orthop. Relat. Res.* 164–172 (1997).

C. Rhinitis

Ms. Trombley had a history of rhinitis, which has been implicated in PJIs. She was taking Sudafed and Zyrtec for these symptoms.

Even though the principal pathogens responsible for rhinitis are viruses and are generally not responsible for SSIs, bacterial microorganisms can be causative. Bacteria can adhere to condensation droplets to form larger aggregates (Colony Forming Units, CFUs) and be infectious in a short-range scenario (less than 1 meter) potentially leading to a SSI.

References:

Edmiston Jr CE, Seabrook GR, Cambria RA, Brown KR, Lewis BD, Sommers JR, et al. Molecular epidemiology of microbial contamination in the operat-ing room environment: is there a risk for infection? Surgery 2005;138:573–9.

D. Malnutrition

Ms. Trombley has malnutrition as objectively evidenced by a low serum albumin (3.4), which can be noted on May 7, 2012 as an example.

Multiple reviews have found that the degree of malnutrition correlates with an increased risk of impaired wound healing, persistent wound drainage, and PJIs (See references at end of this section). Lavernia et al. reported that 4.54% of patients with an albumin <3.5 g/dL developed a deep infection versus 2.06% in controls. In another matched cohort study, malnutrition (albumin <3.5 g/dL) was determined to be an independent risk factor for PJI (adjusted OR 3.00, 95% CI 1.56-5.75). In a propensity-matched, retrospective, NSQIP database analysis of 34,800 TKA patients with preoperative albumin levels, Fu et al. found that

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preoperative hypoalbuminemia was a strong predictor for multiple complications. A retrospective cohort-control study of 49,603 TJAs reported the prevalence of hypoalbuminemia to be 4%, placing patients at significantly higher risk of SSI (RR 2.0, 95% CI 1.5-2.8). In a retrospective cohort, Jaberi et al. confirmed that TJA patients with malnutrition were more likely to develop deep PJIs.

Malnutrition is thus a relative contraindication for TJA.

References:

Berbari EF, Hanssen AD, Duffy MC, et al. Risk factors for prosthetic joint infection: case-control study. *Clin Infect Dis*. 1998;27(5):1247-1254.

Bohl DD, Shen MR, Kayupov E, Della Valle CJ. Hypoalbuminemia Independently Predicts Surgical Site Infection, Pneumonia, Length of Stay, and Readmission After Total Joint Arthroplasty. *J Arthroplasty*. 2016;31(1):15-21. doi:10.1016/j.arth.2015.08.028.

Courtney PM, Rozell JC, Melnic CM, Sheth NP, Nelson CL. Effect of Malnutrition and Morbid Obesity on Complication Rates Following Primary Total Joint Arthroplasty. *J Surg Orthop Adv*. 2016;25(2):99-104.

Cross MB, Yi PH, Thomas CF, Garcia J, Della Valle CJ. Evaluation of Malnutrition in Orthopaedic Surgery. *J Am Acad Orthop Surg*. 2014;22(3):193-199. doi:10.5435/JAAOS- 22-03-193.

Del Savio GC, Zelicof SB, Wexler LM, et al. Preoperative nutritional status and outcome of elective total hip replacement. *Clin Orthop Relat Res*. 1996;(326):153-161.

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Lavernia CJ, Sierra RJ, Baerga L. Nutritional Parameters and Short Term Outcome in Arthroplasty. *J Am Coll Nutr*. 1999;18(3):274-278. doi:10.1080/07315724.1999.10718863.

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Walls JD, Abraham D, Nelson CL, Kamath AF, Elkassabany NM, Liu J. Hypoalbuminemia More Than Morbid Obesity is an Independent Predictor of Complications After Total Hip Arthroplasty. *J Arthroplasty*. 2015;30(12):2290-2295. doi:10.1016/j.arth.2015.06.003.

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E. Renal Disease

Ms. Trombley suffered from renal disease at the time of her procedure. She had a creatinine of 1.3. This disease was also noted by Dr. Beer in his deposition.

Patients with kidney disorders have been found to have an increased risk for PJIs. Cavanaugh et al. found that primary total joint replacement patients with kidney disease had a significantly increased risk for SSI when compared to controls (OR 1.59; 95% CI 1.14-2.21).

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Cavanaugh PK, Chen AF, Rasouli MR, Post ZD, Orozco FR, Ong AC. Total Joint Arthroplasty in Transplant Recipients: In-Hospital Adverse Outcomes. *J Arthroplasty*. 2015;30(5):840-845. doi:10.1016/j.arth.2014.11.037.

F. Corticosteroid Usage

Ms. Trombley was taking Prednisone 10 mg per day, which would increase her risk for a PJI.

A meta-analysis of four studies have shown that corticosteroid treatment is associated with an increased risk of PJI following TKA. Zhu and colleagues also demonstrated corticosteroid steroid therapy to be associated with an increased risk in a pooled analysis of five studies. These prior two studies are consistent with a more recent pooled analysis of 10 studies.

References:

Chen J, Cui Y, Li X, et al. Risk factors for deep infection after total knee arthroplasty: A meta-analysis. *Arch Orthop Trauma Surg*. 2013;133(5):675-687. doi:10.1007/s00402-013- 1723-8.

Kunutsor SK, Whitehouse MR, Blom AW, Beswick AD. Patient-related risk factors for periprosthetic joint infection after total joint arthroplasty: A systematic review and meta-analysis. *PLoS One*. 2016;11(3):e0150866. doi:10.1371/journal.pone.0150866.

Zhang F, Chen W, Liu S, Zhang Q, Zhang Y. Risk factors for periprosthetic joint infection after total joint arthroplasty: a systematic review and meta-analysis. *J Hosp Infect*. 2015;89(2):82-89. doi:10.1016/j.jhin.2014.10.008.

G. Diabetes Type 2

Ms. Trombley had Diabetes Type 2.

Outcomes in general have shown that diabetic patients have an increased risk for PJI. In a retrospective cohort study of 56,216 knees, diagnosis of diabetes was reported to confer a 1.28 (HR; 95CI 1.03-1.60) greater risk for PJI when compared to non-diabetic controls (Namba et al.)

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In a Chinese study of 1133 TKAs by Lee et al., PJI was reported to be 6.07 greater (OR; 95% CI 1.43–25.75) for infection when compared to unmatched controls. In a separate study based on Chinese patients, Wu et al. showed an adjusted risk for PJI of 5.47 (95% CI: 1.77–16.97) over controls. Several meta-analyses of have also reported a significantly elevated rate of PJI within the diabetic population (see references at end of section).

I am not aware of any studies that show that tight glycemic control reduces the higher rates of PJI.

Also, Mrs. Trombley's glucose levels during the hospital stay ranged between 110 and 140s; normal should typically be less than 100.

In addition, Ms. Trombley does not follow her diabetic diet at home; thus, one cannot know how well she was controlled after she left the hospital.

References:

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H. Her Increased body mass index (BMI) is based on the fact that she was 5 feet 3 inches tall and weighed 212 pounds, giving her a body mass index [BMI] of 37.55, which is Class 2 obesity, just under morbidly obese.

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It is well-known that obesity increases the risk of a periprosthetic joint infections. A recent meta-analysis examining the influence of obesity on complications following TKA concluded that patients who had a BMI≥30 Kg/m^2 are at increased risk for infection (Kerkhoffs et al.). Two recent high evidence studies used their large institutional databases (approximately 20,000 patients in each institution) to show a 10% increased risk for periprosthetic joint infection for each BMI unit above normal (25 Kg/m^2)Wagner et al., Shohat et al. Shohat and co-authors showed a linear increased risk with higher BMI, with no distinct cut-off that was different than random chance.

Werner et al. analyzed postoperative outcomes of 891,567 patients undergoing total hip arthroplasty, who were stratified into 4 cohorts: non-obese (BMI <30 kg/m^2); obese (BMI 30-40 kg/m^2); morbidly obese (BMI 40 to 50 kg/m^2); and super-obese (BMI >50 kg/m^2). The risk of surgical site infections increased with increasing BMI, and was found to be 0.8% in the non-obese, 2.6% in the obese, 5.2% in the morbidly obese, and 12.4% in the super-obese.

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I. American Society of Anesthesiologist (ASA) Grade of 3

An ASA grade of > 2 is associated with an increased risk of periprosthetic joint infections in multiple studies, some of which are listed below:

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J. Opioid/Narcotic Usage

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The use of opioids prior to surgery has been associated with an increased risk of developing periprosthetic joint infections. This usage was part of Ms. Trombley's history as she was on Vicodan as needed and took Tylenol #4, 1.5 tablets twice a day, on a chronic basis.

The following will review the evidence for this assertion of opioid usage related to periprosthetic joint infections.

In cell culture studies, animal models, and human scenarios, opioids have been shown to have immunosuppressive effects and to lead to infections (Sacerdote, Egydio et al., Liang et al., Wang et al., Roy et al., Breslow et al., Mora et al, Schwacha et al.).

Menendez et al. found that preoperative opioid use was associated with an increased risk of surgical site infections. Cancienne et al. found in a national database review that preoperative narcotic use was associated with a higher risk of periprosthetic joint infection within 1 year. Bell et al. also found, in a retrospective case-control study, that preoperative opioid usage was independently associated with an increased risk of PJI.

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K. Pre-operative Anemia

Pre-operative anemia is a risk factor for periprosthetic joint infections. Ms. Trombley had a hemoglobin of 11.9 going into the procedure, which is anemic (Normal 12 to 15.5). It was also recorded by CRNA Peterson as being 11.2 at the time of the procedure, which is even lower. This was also noted by Dr. Beer in his deposition. This would be considered an iron deficiency anemia for which she was taking daily iron supplementation.

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Preoperative anemia, as defined by the World Health Organization (WHO) as a hemoglobin of less than 12.0 g/dl in women, is an independent risk factor for periprosthetic joint infections. There are multiple studies that support this increased risk of infection with anemia (Goodnough et al., Eka and Chen, Greenky et al., Swenson et al., Vika et al. , Bozic et al. -2 studies, Klement et al.).

Two studies by by Bozic et al., revealed an Adjusted Hazard Ratio for anemia in TJA to be 1.36 and 1.26, respectively ($p=0.0347$ and $p=0.0014$). In a level III study, Greenky et al. found anemia to be independently associated with an adjusted odds ratio of 1.95 (1.38-2.56) for the risk of periprosthetic joint infection.

To the best of my knowledge, no studies have investigated whether increasing preoperative hemoglobin without correcting the underlying cause of anemia decreases the risk of postoperative periprosthetic joint infections posed by active anemia.

References:

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Bozic KJ, Lau E, Kurtz S, Ong K, Rubash H, Vail TP, et al. Patient-related risk factors for periprosthetic joint infection and postoperative mortality following total hip arthroplasty in Medicare patients. The Journal of bone and joint surgery American volume. 2012;94: 794-800.

Spahn DR. Anemia and patient blood management in hip and knee surgery: a systematic review of the literature. Anesthesiology. 2010;113: 482-95.

L. Vitamin D Deficiency

Vitamin D Deficiency, which Ms. Trombley presumably had because it goes hand –in-hand with a magnesium deficiency, may increase the risk of periprosthetic joint infections by diminishing vitamin D-mediated innate and adaptive immune responses.

The vitamin has been shown to activate the innate immune system to kill bacteria through intracrine regulation of monocytes, as well as by modulating production of anti-microbial cytokines (Hewison, Youssef et al.).

Maier et al. prospectively studied serum 25-hydroxyvitamin D levels in arthroplasty patients and found deficiencies in 64% of primaries, 52% who had aseptic loosening vs. 86% who had periprosthetic joint infections, a statistically significant difference. A retrospective case-control study of revision total joint arthroplasties had similar findings, with periprosthetic joint infection patients being more likely to have vitamin D deficiency than patients being revised for aseptic indications (72.7 vs 48.4%, respectively) (Travison et al.).

References:

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Traven SA, Chiaramonti AM, Barfield WR, Kirkland PA, Demos HA, Schutte HD, Drew JM. Fewer Complications Following Revision Hip and Knee Arthroplasty in Patients With Normal Vitamin D Levels. J Arthroplasty. 2017;32(9S):S193-S196.

M. Referral about great toe—Beer deposition on page 22.

There is a reference to an issue with her right great toe for which she required treatment with a podiatrist. The nature of this issue is not further explained; however, depending on the nature of the problem, it could potentially involve a source of bacterial contamination of the knee joint.

N. Hypertension

Ms. Trombley had this risk factor, which has been correlated to increased PJI risk.

Zhu Y, Zhang F, Chen W, Liu S, Zhang Q, Zhang Y. Risk factors for periprosthetic joint infection after total joint arthroplasty: A systematic review and meta-analysis. J Hosp Infect 2015;89:82–9. doi:10.1016/j.jhin.2014.10.008.

O. Hypercholesterolenemia

Ms. Trombley had this risk factor, which has been correlated to increased PJI risk.

Zhu Y, Zhang F, Chen W, Liu S, Zhang Q, Zhang Y. Risk factors for periprosthetic joint infection after total joint arthroplasty: A systematic review and meta-analysis. J Hosp Infect 2015;89:82–9. doi:10.1016/j.jhin.2014.10.008.

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P. Recurrent Urinary Tract Infections

Ms. Trombley had this risk factor, which has been correlated to increased PJI risk.

Zhu Y, Zhang F, Chen W, Liu S, Zhang Q, Zhang Y. Risk factors for periprosthetic joint infection after total joint arthroplasty: A systematic review and meta-analysis. J Hosp Infect 2015;89:82–9. doi:10.1016/j.jhin.2014.10.008.

3. Infection Risk Calculation

There have recently been described different risk calculators for periprosthetic joint infections. For example, there is the Total Joint Replacement Risk Calculator (TJRRC) from the American Joint Replacement Registry (from the American Academy of Orthopaedic Surgeons) risk calculator (available at http://riskcalc.aaos.org/calculator.php)

Using this risk calculator, Mrs. Trombley would have a baseline 1.30% risk (range, 1.07 to 1.58%) of getting a periprosthetic knee infection within 2 years if she had no comorbidities. With her comorbidities (height and weight, anemia, diabetes, drug abuse, electrolyte disorder, vitamin D deficiency, hypercholesterolenemia, hypertension, renal disease, rheumatological, urinary tract infection), she had an approximately 3.5 fold increased risk.

I also used the International Consensus Meeting lifetime periprosthetic joint infection calculator based on the 2018 publication by Tan and colleagues (second reference below). The calculation takes into account the patient's body mass index (BMI), sex, insurance status (Medicare/Medicaid vs. other), surgery type, number of prior surgeries, and key comorbidities. I utilized Ms. Trombley's patient specific factors: BMI: 37.55; sex: female; insurance; positive history of drug abuse; surgery type: primary TKA; and comorbidities: deficiency anemia, diabetes, renal disease, and rheumatologic. Of note, we excluded other factors such as American Society of Anesthesiologists Class 3 grade, as these were not included variables in this calculator. Based on the included patient specific factors, the patient has a lifetime PJI risk of 43.92%, substantially increased from a 0.9% risk for a patient with minimal risk factors (BMI: under 30; female; non-smoker; no drug abuse history; primary TKR; no prior procedures).

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Tan TL, Kheir MM, Chen AF. Who is at Risk for Periprosthetic Joint Infection? In: Kendoff D, Morgan-Jones R, Haddad FS, editors. Periprosthetic Joint Infections. Changing Paradigms. Swizerland: Springer; 2016. 61-75.

Tan TL, Maltenfort MG, Chen AF, Shahi A, Higuera CA, Siqueira M et al. Development and evaluation of a preoperative risk calculator for periprosthetic joint infection following total joint arthroplasty. J Bone Joint Surg Am 2018; 100:777-785.

The Type of Infection and other Factors Make this PJI Unlikely to have Occurred Intraoperatively

My opinion is that the inoculation occurred postoperatively, possibly from scratching of the wound, direct contact with an incompletely healed would, or late hematogenous seeding (most likely). An intraoperative source is extremely unlikely for many reasons. Of note, Group B Streptococcal Infections (GBS) do not typically occur from intraoperative contamination. I am not aware of any studies that have demonstrated that GBS is a common airborne pathogen in orthopaedic operating rooms, nor would I expect it to be. GBS bacteria are extremely virulent organisms; thus, Mrs. Trombley's acute onset more than 30 days after the surgery strongly indicates post-operative inoculation.

Traditionally, GBS bacteria were associated with pregnant women and neonates. Recently, there has been an increasing incidence in non-pregnant adults. Currently, GBS infections represent perhaps 3% of all PJIs, possibly more.

Jenkins and co-authors recently reviewed PJIs from Streptococcus organisms. They stated that Streptococcus in general are now being found in increasing numbers (approximately 10%), and are most commonly from secondary (hematogenous) spread.

An article by Sendi and co-authors from various hospitals in Switzerland and Sweden described recent trends in the epidemiology of Group B Streptococcus.

They found 36 cases from 10 centers: most were diagnosed (>75%) greater than 3 months after implantation. In 34 cases, 20 attempts were made to retain the prosthesis with 5

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failures. The other 14 went right to removal, so overall 15/34 or 45% were successful at being retained.

Overall, 94% of the infections were cured with 82% functional mobility preserved. In addition, 10 of 10 were successful if duration was short and soft tissue minor at retention of prostheses. Only 9% of patients had no comorbidities. The Sendi report describes a 3% frequency as well, but it is increasing. In their Medline search, they found 75 other cases, with over 30 references. There is a CDC report denoting that the prevalence of GBS in non-pregnant adults has tripled in 30 years.

My opinion that inoculation did not occur intraoperatively is based on the following:

1. Since this is a virulent organism, one would have expected onset of symptoms almost immediately post-operatively or at most within a few days. In fact, when Dr. Beer checked her at the December 15, 2011 visit, she was doing fine with her knee and the wound. He found no evidence of infection.

2. Her wound is described as clean and dry and not draining at this point by Dr. Beer in his notes and confirmed at his deposition (page 57).

3. During this December 15 visit, he describes the incision as:

   "clean dry and intact, below knee ecchymosis—lower leg and calf---mild to moderate. This is very common." (Pages 58-59)

   He notes that the swelling and localized hematoma of the medial tibial condyle were really insignificant. At this point, he doesn't suspect any evidence of an infection. No warmth, induration, or erythema noted.

4. When she appears several weeks later with approximately 3 days of drainage, Dr. Beer cannot aspirate any fluid from the prosthetic knee joint. This is important because an experienced orthopaedic surgeon such as Dr. Beer would certainly have had no difficulty in aspirating fluid in the joint if there had been any, and the absence of any collection of deep fluid strongly demonstrates that the joint itself, to the extent it had by that point

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become infected, had been inoculated from the superficial skin area where he was able to obtain culturable pus.

5. Although Dr. Beer on page 71, states that "I can't tell for sure when she got it," he testified that it is most likely that the inoculation occurred three weeks after the initial surgery. I agree with his assessment.

6. When Dr. Beer is asked about his basis for speculating vs. an Infectious Diseases expert he states on pages 98-99 of his deposition:

> Question: Do you have as much basis for stating the timing of the infection here as a Board Certified infectious disease doctor?
> Dr. Beer: Yes. Q. And on what basis would that be? Dr. Beer: Well, because I know what the wound looked like two weeks postop and what it looked like six weeks postop and they don't.

In addition, he found that the knee was more purulent on the outside as will now be elaborated. Dr. Beer is in a unique position to draw this conclusion. He is not only an experienced orthopaedic surgeon: he is the surgeon who actually performed the initial surgery, saw her at two weeks and six weeks post operatively, and performed the explantation surgery and treated the infection.

7. A recently acquired infection is supported from evidence found by Dr. Beer during his visual inspection: A pus pocket was found superficially in the incision, but nothing in the deeper layers or in the joint by visual inspection. He concluded based on his actual examination that the infection migrated from outside in.

8. What Dr. Beer described is not consistent with Streptococcal organisms migrating from the joint replacement outwards as would happen if the joint had been inoculated intraoperatively.

9. This is further supported by the laboratory findings from samples collected at each layer:
    a. Superficial Wound (drawn 1/10/12) Gram stain: 0-1 WBCs, many Gram positive cocci; Culture: moderate GBS.

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b. Right knee synovium tissue (drawn 1/11/12) Gram stain: 10-24 WBCs, no organisms seen. Culture: few GBS; anaerobic culture: rare GBS, no anaerobes
c. Surgical/deep wound: Gram stain: 0 WBCs, no organisms seen. Culture: rare GBS; anaerobic culture: rare GBS, no anaerobes.

This represents an inverted pyramid of contamination from superficial to deep: moderate GBS at the top, few GBS in the middle, and rare GBS in the joint. This indicates that the joint replacement was inoculated from the superficial layer down and had not had sufficient growth time to develop more than "rare" amounts of GBS bacteria.

10. Obtaining fluid from a knee joint is not like a hip replacement: it is close to the skin and easy to obtain.

11. Even though the joint replacement was minimally involved, Dr. Beer felt it was wise to remove it all because of Ms. Trombley's comorbidities including her immunosuppressed status (use of Prednisone, etc.)

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Sendi et al. J Hospital Infection:79:2011

4. Maintenance of normothermia is important

We must acknowledge the importance of maintaining patient normothermia for surgical procedures. Medications used during general and epidural anesthesia alter the body's thermoregulatory control and can result in hypothermia (Sessler et al). Various animal studies have demonstrated that intraoperative hypothermia may decrease resistance to some pathogens. (Sheffield et. al, 2 reports). Hypothermia and secondary vasoconstriction may also lead to reduced oxygen delivery to tissues and increase the risk of infectious complications (Wartig et al., Kurz et al. , and Melling et al.). Several well-designed studies have attributed a significant decrease in surgical site infection rates in colorectal and non-orthopaedic surgeries with normothermia (Kurz et al., Melling et al.) Current guidelines from the World Health Organization (WHO) and Centers for Disease Control and Prevention recommend active measures to prevent hypothermia to reduce the risk of surgical site infections and other complications associated with surgery (Berríos-Torres et al., WHO).

Plaintiff's counsel have argued that intra-operative warming is not necessary for surgeries that take under two hours to perform. There is simply no valid scientific basis for this claim. In the case of Ms. Trombley, the procedure lasted 71 minutes and her in-room time in the OR was over two hours. Moreover, there would be no way to predict ahead of time exactly how long this procedure would take. At best, any surgeon can only make an educated guess. A surgical procedure like Ms. Trombley's can frequently takes longer than 2 hours, depending on many variables (e.g. dropped instrument(s) that needs to be flash-sterilized, excessive bleeding that needs more time for hemostasis, etc.) - many of these issues cannot be anticipated at the beginning of the procedure. It would not be appropriate to assume that a knee replacement would take less than 2 hours. In addition to the important role that intraoperative warming plays in reducing the risk of infection, it serves a multitude of other functions, even in the first hour;

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e.g., positive impact on core temperature and patient comfort, which can prevent further cutaneous heat loss and which in its absence could lead to many other complications.

In Ms. Trombley's surgery, the records reflect that her temperature remained essentially constant throughout the surgery and she did not experience the dangerous decrease and recovery that can happen in the absence of active warming.

During the CRNA deposition, Lauren Peterson on page 44 describes that hypothermia prevents shivering, hemodynamic instability, and in combination with Ms. Trombley's diabetes mellitus hypothermia, could have compromised her ability to heal.

On Page 57, Mr. Peterson states that normothermia was maintained throughout Ms. Trombley's procedure (36 being the low end of normal).

Of note is that Dr. Beer always uses a Bair Hugger device on his 275 to 300 joint replacement cases per year (Pages 18-19 of his deposition) and has an extremely low infection rate (0.3%) as per his deposition (Page 27).

References:

Sessler DI. Perioperative thermoregulation and heat balance. Lancet. 2016 Jun 25;387(10038):2655-64.

Sheffield CW, Sessler DI, Hunt TK. Mild hypothermia during isoflurane anesthesia decreases resistance to E. coli dermal infection in guinea pigs. Acta Anaesthesiol Scand. 1994 Apr;38(3):201-5.

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Warttig S, Alderson P, Campbell G, Smith AF. Interventions for treating inadvertent postoperative hypothermia. Cochrane Database Syst Rev. 2014:CD009892.

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Melling AC, Ali B, Scott EM, Leaper DJ. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. Lancet. 2001;358(9285):876-880.

Berríos-Torres SI, Umscheid CA, Bratzler DW, et al.; Healthcare Infection Control Practices Advisory Committee. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017 Aug 1;152(8):784-791

World Health Organization. Global Guidelines for the prevention of Surgical Site Infection. Geneva, Switzerland: World Health Organization;2016.

5. **It is highly unlikely that this infection was caused intra-operatively, but one must realize that the major source of risk in the operating room setting is the patient themselves because of their skin-resident bacteria.**

This has been discussed extensively in my general cause report. Preoperative preparation of skin with antiseptics reduces the number of microorganisms on the skin, but cannot completely get rid of them. When the skin is incised, bacteria that colonize the deeper layers of the skin can contaminate the exposed tissues and lead to a periprosthetic joint infection.

Even if one assumes that inoculation occurred intraoperatively, there are many factors that could have led to the infection in Ms. Trombley's case. On the top of the list would be her own bacteria as described above. This would be followed by direct contact of bacteria at the operative site or field by the surgeon and direct participating staff.

As Dr. Beer states in his deposition on page 95: "The whole environment poses some risk."

Next would be direct contamination of the instruments or implant during the procedure. After this, airborne bacteria can be a possible source. As discussed below, there are many potential sources of airborne bacteria during a surgery. Furthermore, we cannot forget that the

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infection may have arisen at any time during the perioperative period outside of the operating room (e.g. from the pruritic scratching, from the bandaged wound, etc.). There is no scientific basis for determining which one of these many possibilities could be the source of the infection, even if the unlikely intra-operative contamination occurred.

6. **There were many other machines, equipment, persons, that could potentially increase the risk to a patient of an infection in any joint arthroplasty and are known published risk factors.**

Once again, I will repeat from the operating surgeon: As Dr. Beer states in his deposition on page 95: "The whole environment poses some risk."

I have included an extensive list in previous reports, but will add the following:

1. **Light handles** are a possible source of contamination during orthopaedic procedures. The following description and reports provide confirmatory evidence for this statement:

---Davis et al. found that 14.5% of light handles were contaminated during primary hip and knee arthroplasties.

--- Richard et al. used a novel method - adenosine triphosphate bioluminescence technology- in detecting the degree of contamination. They concluded that several surfaces including light handles had bioburden and contaminated operating room surfaces can increase the risk of orthopaedic infections.

---Romero et al. showed that placement of surgical light handles produced moderate particle contamination of the sterile field.

---- Schweitzer et al. screened 36 light handles in hip arthroplasty surgery for bacterial contamination and found that 50% yielded positive cultures.

---The International Consensus on Periprosthetic Joint Infection and a meta-analysis by Ratto et al. concluded that light handles can be a source of contamination and surgeons must minimize their handling as much as possible.

Adjusting the lights can also disrupt laminar flow during the case close to the operative site.

References:

Davis N, Curry A, Gambhir AK, Panigrahi H, Walker CR, Wilkins EG, Worsley MA, Kay PR.

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Richard RD, Bowen TR. What Orthopaedic Operating Room Surfaces Are Contaminated With Bioburden? A Study Using the ATP Bioluminescence Assay. Clinical Orthopaedics and Related Research. 2017 Jul;475(7):1819-182

Romero JA, Landrum M, Swann M, Brown T, Huo MH. Intraoperative Surgical Light Movement is a Potential Source of Sterile Field Contamination. In: American Academy of Orthopaedic Surgeons Annual Meeting Proceedings. San Diego; 2017.

Ratto N, Arrigoni C, Rosso F, Bruzzone M, Dettoni F, Bonasia DE, Rossi R. Total knee arthroplasty and infection: how surgeons can reduce the risks. EFORT Open Reviews. 2016 Sep; 1(9): 339–344

Schweitzer D, Klaber I, Fischman D, Wozniak A, Botello E, Amenábar PP. Surgical light handles: a source of contamination in the surgical field. Acta Orthopaedica et Traumatologica Turcica. 2015;49(4):421-5.

Parvizi J, Gehrke T, Chen AF. Proceedings of the International Consensus on Periprosthetic Joint Infection. The Bone & Joint Journal. 2013 Nov;95-B:1450–2.

2. **Bacteria are present or settle on many of the tools, devices, etc. found in the operating room during the procedure:**

Knobben et al. studied the transfer of *Staphylococcus aureus*, *Staphylococcus epidermidis,* and *Propionibacterium acnes* from one operating room material (gloves, orthopaedic drills, operating room gowns, and light handles) to another. Transfer was demonstrated with all bacterial strains and with every material ranging from 17 to 71%.

References:

Knobben BA, van der Mei HC, van Horn JR, Busscher HJ. Transfer of bacteria between biomaterials surfaces in the operating room- an experimental study. Journal of Biomedical

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Materials Research Part A. 2007 Mar 15;80(4):790-9.

3. Gloves can be a source of contamination, both directly and when perforated.

Therefore, changing gloves frequently during cases is advocated by many to address this potential source of bacterial contamination.

For example, there are advocates for glove changing after draping, before handling implants, and when macroscopic perforation occurs. It has been suggested that gloves can also be changed at least once every 60 minutes, as glove perforation rates and bacterial contamination increase with surgery duration (Bukhari et al.).

The evidence shows that multiple studies demonstrate contamination of surgical gloves in joint arthroplasty, ranging from 3.4 to 30% (Ward et al., McCue et al., Ritter et al., Davis et al., Beldame et al., Al-Maiyah et al.).

Changing gloves helps. Ward et al., in a randomized trial of 102 surgical team members, demonstrated significantly decreased contamination rates when gloves were changed one hour into a clean orthopaedic procedure versus when gloves were retained (13 vs. 23%).

In a randomized, controlled trial, Al-Maiyah et al. compared two study groups; one in which surgeons changed gloves every 20 minutes during total hip arthroplasty and another in which surgeons only changed gloves at the time of component implantation. They demonstrated a significant reduction in perforation and contamination in the former group.

References:

Bukhari SS, Harrison RA, Sanderson PJ. Contamination of surgeons' gloves fingertips during surgical operations. J Hosp Infect. 1993;24:117-21.

Ward WG, Cooper JM, Lippert D, Kablawi RO, Neiberg RH, Sherertz RJ. Glove and gown effects on intraoperative bacterial contamination. Ann Surg. 2014;259(3):591–7.

McCue SF, Berg EW, Saunders EA. Efficacy of double-gloving as a barrier to microbial

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Ritter MA, French ML, Eitzen H. Evaluation of microbial contamination of surgical gloves during actual use. Clin Orthop Relat Res. 1976;(117):303-6.

Davis, N, Curry, A, Gambhir, AK, Panigrahi, H, Walker, CR, Wilkins, EG, et al. Intraoperative bacterial contamination in operations for joint replacement. J Bone Joint Surg (Br). 1999;81(5):886-9.

Beldame J, Lagrave B, Lievain L, Lefebvre B, Frebourg N, Dujardin F. Surgical glove bacterial contamination and perforation during total hip arthroplasty implantation: when gloves should be changed. Orthop Traumatol Surg Res. 2012;98(4):432-40.

Al-Maiyah, M, Bajwa, A, Mackenney, P, Port, A, Gregg, PJ, Hill, D et al. Glove perforation and contamination in primary total hip arthroplasty. J Bone Joint Surg (Br). 2005;87(4):556- 9.

Other studies relevant to glove perforation and timing of glove changes to avoid bacterial contamination in knee arthroplasty as well as in other surgical specialties include:

Dawson-Bowling S, Smith J, Butt D, Cottam H, Umasankar S, Armitage A. Should outer surgical gloves be changed intraoperatively before orthopaedic prosthesis implantation? J Hosp Infect. 2011;78(2):156-7.

Misteli, H, Weber, WP, Reck, S, Rosenthal, R, Zwahlen, M, Fueglistaler, P, et al. Surgical glove perforation and the risk of surgical site infection. Arch Surg. 2009;144(6):553-8.
Kaya I, Uğraş A, Sungur I, Yilmaz M, Korkmaz M, Cetinus E. Glove perforation time and frequency in total hip arthroplasty procedures. Acta Orthop Traumatol Turc. 2012;46(1):57- 60.

Demircay E, Unay K, Bilgili MG, Alataca G. Glove perforation in hip and knee arthroplasty. J Orthop Sci. 2010;15(6):790-4.

Al-Habdan I, Sadat-Ali M. Glove perforation in pediatric orthopedic practice. J Pediatr Orthop. 2003;23(6):791-3.

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Carter AH, Casper DS, Parvizi J, Austin MS. A prospective analysis of glove perforation in primary and revision total hip and total knee arthroplasty. J Arthroplasty. 2012;27(7):1271-5.

Rehman A, Rehman AU, Rehman TU, Freeman C. Removing Outer Gloves as a Method to Reduce Spinal Surgery Infection. J Spinal Disord Tech. 2015;28(6):343-6.

Zdanowski Z1, Danielsson G, Jonung T, Norgren L, Ribbe E, Thörne J, et al. Intraoperative contamination of syn-thatic vascular grafts: effect of glove change before graft implantation: a prospective randomised study. Euro J Vasc Endovasc Surg. 2000;19:283-7.

4. Surgical gowns can also be a source of bacterial contamination during a total knee arthroplasty or any procedure.

Bible et al. assessed the sterility of various parts of a surgical gown during spine procedures. After an average duration of 134 minutes, the contamination rate of impermeable disposable gowns ranged from 6 to 48%. Also, Flaherty et al. demonstrated that the permeability of gowns increases after contact with blood after one hour, potentially increasing contamination.

References:

Bible JE, Biswas D, Whang PG, Simpson AK, Grauer JN. Which regions of the operating gown should be considered most sterile? Clinical orthopaedics and related research. 2009;467: 825-30.

Flaherty AL, Wick TM. Prolonged contact with blood alters surgical gown permeability. American journal of infection control. 1993;21: 249-56.

5. Trays for instruments can get contaminated during the procedure.

Dalstrom et al, demonstrated a time-dependent contamination of open sterile trays on the back table with 4% of trays contaminated at 30 minutes, 15% contaminated at 1 hour, 22% at 2 hours, and 30% at 4 hours.

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6. **The electrocautery tip(s) used during surgery can be a source of bacterial contamination.**

Contamination of electrocautery tips was noted in dermatology, when it was shown that *Staphylococcus* aureus could transfer from tissue to sterile tips and vice versa (Bennett and Kraffert). Shahi et al. collected electrocautery tips from 25 primary and 25 aseptic revision total hip arthroplasties and inoculated them in culture. Five unused electrocautery tips were also inoculated as negative controls. Cultures isolated an organism in 4% of primary and 8% from aseptic revision total hip arthroplasty tips. No organisms were isolated from the unused tips. Abdelaziz reported a 10% rate of contamination for primary total hip and knee arthroplasties. All negative controls in their study also failed to isolate an organism on culture.

References

Bennett RG, Kraffert CA. Bacterial transference during electrodesiccation and electrocoagulation. Arch Dermatol 1990;126:751–5.

Shahi A, Chen AF, McKenna PB, Roberts AL, Manrique J, Belden KA, et al. Bacterial Contamination in Tips of Electrocautery Devices During Total Hip Arthroplasty. J Arthroplasty 2015;30:1410–3. doi:10.1016/j.arth.2015.03.011.

Abdelaziz H, Zahar A, Lausmann C, Gehrke T, Fickenscher H, Suero EM, et al. High bacterial contamination rate of electrocautery tips during total hip and knee arthroplasty. Int Orthop 2018. doi:10.1007/s00264-018-3822-1.

7. **Laminar flow ventilation systems** used in the operating room were designed to reduce infections, as early studies appeared to show.

Recently, there are some studies that show that usage might show no reduction or an increase in periprosthetic infections. Marotte et al. reviewed 2,384 total hip arthroplasties with

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and without laminar air flow and found no differences in sepsis rates between the two settings. van Griethuysen et al. compared infection rates after switching from a conventional operating room to a newer hospital equipped with laminar air flow. They found no statistically significant difference in infection rates (1.2% before, 1.6% after) in 1,687 orthopaedic procedures. Similar results were found in other large national database studies (Singh et al.,Breier et al., and Pinder et al.)

Three recent studies utilizing large national registries have demonstrated an increase in infection after joint arthroplasty using laminar air flow (Brandt et al., Hooper et al., Tayton et al).

References:

Marotte JH, Lord GA, Blanchard JP, Guillamon JL, Samuel P, Servant JP, et al. Infection rate in total hip arthroplasty as a function of air cleanliness and antibiotic prophylaxis. 10-year experience with 2,384 cementless Lord madreporic prostheses. *J Arthroplasty*. 1987;2: 77-82.

van Griethuysen AJ, Spies-van Rooijen NH, Hoogenboom-Verdegaal AM. Surveillance of wound infections and a new theatre: unexpected lack of improvement. *Journal Hospital Infection*. 1996;34: 99-106.

Singh S, Reddy S, Shrivastava R. Does laminar airflow make a difference to the infection rates for lower limb arthroplasty: a study using the National Joint Registry and local surgical site infection data for two hospitals with and without laminar airflow. *European Journal of Orthopaedic Surgery Traumatology* 2017;27: 261-65.

Breier AC, Brandt C, Sohr D, Geffers C, Gastmeier P. Laminar airflow ceiling size: no impact on infection rates following hip and knee prosthesis. *Infection Control and Hospital Epidemiology*. 2011;32: 1097-102.

Pinder EM, Bottle A, Aylin P, Loeffler MD. Does laminar flow ventilation reduce the rate of infection? an observational study of trauma in England. *Bone Joint Journal*. 2016;98-b: 1262-9.

Brandt C, Hott U, Sohr D, Daschner F, Gastmeier P, Ruden H. Operating room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and

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abdominal surgery. Annals Surgery. 2008;248: 695-700.

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Tayton ER, Frampton C, Hooper GJ, Young SW. The impact of patient and surgical factors on the rate of infection after primary total knee arthroplasty: an analysis of 64,566 joints from the New Zealand Joint Registry. *Bone Joint Journal.* 2016;98-b: 334-40.

8. Mobile Phones

Mobile phones used in the operating room are another potential source of bacterial contamination.

Non-medical electronic equipment, such as cell phones and mobile handheld devices, have become increasingly integrated into the practice of healthcare workers (Mark et al., Manning et al.). Studies have shown that 33 to 88% of healthcare workers admit to using cell phones in operating rooms (Shakier et al., Murgier et al.).

Many studies have described bacterial contamination of the mobile phones of healthcare workers (Ulger et al.) The bacterial species most frequently isolated from the cell-phones are coagulase-negative staphylococci and *Staphylococcus aureus* (Mark et al., Ulger et al., Chang et al.). In the studies performed in operating rooms, the mobile phone contamination rate with possible clinical pathogen varied from 0% to 83%.

References:

Mark D, Leonard C, Breen H, Graydon R, O'Gorman C, Kirk S. Mobile phones in clinical practice: reducing the risk of bacterial contamination. Int J Clin Pract. 2014;68(9):1060-4.

Manning ML, Davis J, Sparnon E, Ballard RM. iPads, droids, and bugs: Infection prevention for mobile handheld devices at the point of care. Am J Infect Control. 2013;41(11):1073-6.
Shakir IA, Patel NH, Chamberland RR, Kaar SG. Investigation of cell phones as a potential

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Ulger F, Dilek A, Esen S, Sunbul M, Leblebicioglu H. Are healthcare workers' mobile phones a potential source of nosocomial infections? Review of the literature. J Infect Dev Ctries. 2015;9(10):1046-53.

Chang CH, Chen SY, Lu JJ, Chang CJ, Chang Y, Hsieh PH. Nasal colonization and bacterial contamination of mobile phones carried by medical staff in the operating room. PLoS One. 2017;12(5):e0175811.

9. Suction Tips

Suction tips can be a source of bacterial contamination. The risk increases with exposure time, so it is advocated that these are changed regularly during cases, such as every 60 minutes.

Contamination of the suction tip during surgical procedures has been reported [1–7 below]. This can be by direct contamination of the tip by contact with the patient's skin and/or by improper handling by operating team members. In orthopaedics, several studies have reported contamination rates of suction tips as high as 37 to 65%. Staphylococcus species (coagulase negative and epidermidis) were the dominating contaminants isolated from suction tips, comprising from 34 up to 100% of cases.

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Insull PJ, Hudson J. Suction tip: a potential source of infection in clean orthopaedic procedures. ANZ J Surg 2012;82:185–6. doi:10.1111/j.1445-2197.2011.05949.x.

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Givissis P, Karataglis D, Antonarakos P, Symeonidis PD, Christodoulou A. Suction during orthopaedic surgery. How safe is the suction tip? Acta Orthop Belg 2008;74:531–3.

Robinson AH, Drew S, Anderson J, Bentley G, Ridgway GL. Suction tip contamination in the ultraclean-air operating theatre. Ann R Coll Surg Engl 1993;75:254–6.

Greenough CG. An investigation into contamination of operative suction. J Bone Joint Surg Br 1986;68:151–3.

Meals RA, Knoke L. The surgical suction top--a contaminated instrument. J Bone Joint Surg Am 1978;60:409–10.

10. Scalpels

Even using the scalpel properly can be a source of unwanted bacterial inoculum; simply by cutting through the skin, a pathway is open for sub-surface bacteria to inoculate the wound. Therefore, the scalpel should be changed after making the skin incision because studies have demonstrated that bacteria from the superficial planes of the skin can contaminate the blade and be a source of potential transfer into deeper tissues.

As stated multiple times, preoperative preparation of skin with antiseptics reduces the number of microorganisms on the skin, but cannot completely eradicate them. When the skin is incised, bacteria that colonize the deeper layers of the skin can contaminate the exposed tissues and may lead to a periprosthetic joint infection (Vivek et al., Schindler et al.)

In one study, the deep knife was significantly more contaminated then the skin knife (Grabe et al.).

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Schindler OS, Spencer RF, Smith MD. Should we use a separate knife for the skin? J Bone Joint Surg Br 2006;88:382–5.

Grabe N, Falstie-Jensen S, Fredberg U, Schroder H, Sorensen I. The contaminated skin- knife: fact or fiction. J Hosp Infect 1985;6:252–6.

11. Space Suits

Dr. Beer describes the use of a space suit since 1982 (Deposition page 36). This can potentially increase risk of PJIs.

Space suits are generally used for protection of the staff as well as the patient. There is conflicting evidence on the use of personal protection suits (space suits) on the rate of periprosthetic infections, with some series reporting increased infection rates.

Hooper reported a statistically higher rate of reoperation for infection within the first six months when helmet systems were used: THA - 0.19% with helmet system vs. 0.06% conventional gown, $p<0.0001$, and TKA - 0.24% with helmet system vs. 0.098% conventional, $p<0.001$. Young et al. pooled data from four series and showed a non- statistical significant ($p=0.09$) increase in deep infections (RR 1.67, 95% CI 0.92, 3.05).

References:

Hooper GJ, Rothwell AG, Frampton C, Wyatt MC. Does the use of laminar flow and space suits reduce early deep infection after total hip and knee replacement?: the ten-year results of the New Zealand Joint Registry. J Bone Joint Surg Br, 93:85–90, 2011

Young SW, Zhu M, Shirley OC, Qing W, Spangehl MJ: Do surgical helmet systems or body exhaust suits affect contamination and deep infection rates in arthroplasty? A systematic review. J Arthroplasty, 31:225-233, 2016

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12. Other Instruments and sources of contamination in a Total Knee Replacement

Studies have shown that high-speed cutters in primary hip arthroplasty can produce aerosols (Nogler et al.-3 studies). These aerosols are potentially contaminated with bacteria, and can spread over the operating room and contaminate the environment and all personnel present during the procedure. Other instruments, such as osteotomes and retractors, can propel particles on to the ceiling, operating room lights, or body parts of surgeons or assistants. The particles that contact an unsterile surface such as the ceiling, facial mask, or lights can fall back into the wound and contaminate the surgical field.

Existing literature suggests that splash basins can be contaminated by bacteria (Baird et al., Anto et al.).

References:

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13. Door Openings and Operating Room Traffic

In Ms. Trombley's case, as in virtually all replacements, there would have been multiple door openings. These are not always recorded; we cannot know with certainty how many door

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openings in this particular case, e.g. each time a nurse may have let the room to get something was not recorded. There is much literature recording and demonstrating disruptions of airflow with these door openings, which have been implicated as leading to an increased risk of bacterial contamination.

The number of individuals in the operating room and the door openings during total joint arthroplasty may lead to an increased risk of periprosthetic joint infections (Pulido et al., Bapkin et al., Teter et al., Weiser et al.). The following section will further summarize the evidence for this.

The number of persons in the operating room and the door openings are a source of increased aerosolized particles in the air (Scaltriti et al., Tiade and Gabor, Malinzak and Ritter, Teter et al., Smith et al., Andersson et al.). Ritter et al. found that bacterial counts were 34-fold higher when five or more persons were present, when compared to an empty room.

Door openings can lead to increased contamination in a number of ways. Firstly, door openings are exponentially linked to staff numbers (Hannsen and Rand). Secondly, they can create turbulence and potentially disrupt laminar flow, which could possibly lead to spread of airborne bacteria to the surgical field (Pulido et al., Smith et al., Parikh et al., Panahi et al.)

Andersson et al. showed a positive correlation between traffic flow and air bacterial counts in orthopaedic procedures. They also identified a direct correlation between the number of personnel.. Quraishi et al. demonstrated a direct correlation between activity level of personnel and bacterial immoculation into the surgical field. Also, Lynch et al. showed an exponential relationship between the number of door openings and the numbers of personnel.

Studies have examined the causes of door openings during joint arthroplasty (Panahi et al., Pada et al., Lynch et al., Bedard et al., Patel et al.). The majority of the traffic is from circulating nurses, followed by surgical implant representatives, anesthesia, and orthopaedic staff (Panahi et a., Lynch et al., Bedard et al.). The most frequently reported reasons for door openings are obtaining supplies, instruments, and implants. Also, information dissemination can lead to door openings. Other reasons include scrubbing in and out, staff rotations for breaks, and other administrative reasons (Panahi et al., Lynch et al).

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Knobben et al. found that limiting unnecessary activity and individuals can lead to marked reductions in the incidence of superficial surgical site infections and a non-significant decrease in deep periprosthetic joint infections.

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6. The Bair Hugger has no evidence for increased risk for surgical site infections as enumerated in my previous report:

My previous general cause report and supplements, as well as my trial testimony in Gareis, discussed in detail the basis for my opinion that there is no scientifically valid evidence from which one can conclude that use of the Bair Hugger increases the risk of PJI. I note that there are two recently published summaries (Allen and Jacofsky, Haeberle et al.) that support this conclusion, as well as the 2018 International Consensus Statement.

I am aware of no evidence of air sampling at the time of Ms. Trombley's or any evidence that the Bair Hugger was cultured or identified as a source of bacteria.

In 2017, a study was published in *Orthopaedic Reviews* by Scott Augustine, purporting to find an increased risk of periprosthetic infections in three hospitals that switched from the Bair Hugger to the Hot Dog warming device.

(Augustine SD: Forced-air warming discontinued: periprosthetic joint infection rates drop. *Orthopedic Reviews*, 9:6998, 2017).

I have commented on this on my previous report. In addition, please see Dr. Borak's supplemental report (November 27, 2017), which includes some of the following facts about this study as well:

There were 3 hospitals involved: South Nassau Communities Hospital, Fox Valley, and Ridgeview Medical Center (RMC).

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At RMC, hip procedures were not included, even though the methods say that both hip and knee procedures were included for all hospitals. In addition, data from 2007 were not included.

Of note: The hip data had lower infection rates with the Bair Hugger than the Hot Dog. The author does not report that he excluded hip data or offer reasons for this omission.
Of note: RMC made many changes for their infection protocol; not simply changing the Bair Hugger as described.

Fox Valley---Had no washout period, since there were only monthly reports.

They also excluded 2013 data, which had higher Hot Dog infection rates.

Finally, although included in the study, South Nassau Communities Hospital never even used the Bair Hugger device.

The above facts supplements some of the problems with the study that I had identified in my earlier reports.

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Conclusion:

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In conclusion, in my opinion, the use of the Bair Hugger device in no way caused or contributed to the infection that Ms. Trombley incurred.

All of the above opinions are held to a reasonable degree of medical certainty. I reserve the right to supplement this report should I receive any additional materials.

I declare under penalty of perjury that the foregoing is true and correct.

Michael A. Mont, M.D. 02/14/2019

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